REMARKS

I. Status of the Claims

Claims 8-13 are pending in the present application. Claims 1-7 and 14-20 have been withdrawn from consideration as a result of Applicants election, with traverse, of Group III claims in response to the restriction requirement dated February 4, 2003. Claim 8 has been amended to be commensurate in scope with the proteins listed in Table 1 of the specification in response to written description concerns raised in the present Office Action. Claims 9 and 10 were previously amended to conform with Applicants election of the lysosomal storage disorder Galactosialidosis and protective protein/cathepsin A (PPCA), the corresponding enzyme which is deficient in this disorder, in response to this election of species requirement.

Applicants maintain their traversal of the restriction requirement. Reconsideration and withdrawal of this restriction requirement is respectfully requested for the reasons set forth in the response submitted February 13, 2003. Should this restriction requirement be maintained, Applicants reserve their right to file a petition to the Commissioner under 37 C.F.R. §§1.144 and 1.181 at any time until after final action or allowance of the elected claims to review the propriety of this requirement.

Claim 8, as amended, continues to represent a genus claim linking species claims which must be examined with the elected invention in accordance with linking claim practice as set forth under MPEP §809. Further in accordance with linking claim practice, subject matter currently withdrawn from consideration as a result of the restriction requirement must be rejoined if this linking claim is found to be allowable.

Applicants respectfully request that the present amendment submitted under 37 C.F.R. §1.116 be entered. The present amendment adds no new matter and places the claims in form for allowance. Applicants did not submit this amendment earlier based upon their belief that the unamended claims were sufficiently described, enabled and distinct from the prior art. The

present amendment is submitted in the interest of furthering the prosecution of this application. Applicants reserve the right to pursue subject matter removed from the claims by the present amendment in one or more continuation applications.

II. The Interview

Applicants thank Examiner Fronda for the courteous and helpful telephonic interview held on July 15, 2003. During the interview proposed amendments to the claims were discussed for the purpose of overcoming outstanding rejections.

III. The Specification Provides a Sufficient Written Description of the Claimed Subject Matter

On page 2 of the Office Action the Examiner maintains his rejection of claims 8-13 under 35 U.S.C. §112, first paragraph, asserting that the claims contain subject matter which was not sufficiently described in the specification. Applicants respectfully maintain their traversal of this rejection for reasons of record as supplemented below.

Applicants have claimed pharmaceutical compositions comprising proteins that are unique due to the process used to produce them and not due to their amino acid sequence. As noted in Applicants' response to the prior office action, the structure of these proteins are well known in the art and references to scientific literature and/or Genbank accession numbers disclosing such structures has been provided in the specification (*See*, in particular, Table 1). Because the structure of these proteins are well known in the prior art, Applicants maintain that these structures do not need to be included in the specification and in fact are preferably omitted according to *Hybridtech, Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81, 94 (Fed. Cir. 1986)("a patent need not teach, and preferably omits, what is well known in the art.").

In the present Office Action the Examiner appears to assert that the claims are unacceptable because they may encompass proteins that are not listed in Table 1 of the

specification. Applicants have addressed this concern by amending the scope of claim 8 to include only proteins listed in this table.

The Examiner also asserts that "the specification does not provide a written description of administering any protein of any structure and function to treat any lysosomal storage disorder . . ." Office Action at page 2, par. 5. Applicants disagree with this assertion and submit that the administration of these compositions is sufficiently described, particularly considering the level of knowledge and skill in the art with respect to the administration of compositions of this type. Moreover, this assertion is not relevant to the question of whether the claimed compositions are sufficiently described. Accordingly, this assertion does not support the present rejection.

Reconsideration and withdrawal of this rejection is respectfully requested in view of the amendment to the claims and for the reasons set forth above and in Applicants' prior amendment and response submitted April 4, 2003.

IV. The Claimed Subject Matter is Enabled

On pages 2 and 3 of the Office Action the Examiner maintains his rejection of claims 8-13 under 35 U.S.C. §112, first paragraph, asserting that the claimed subject matter is not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicants respectfully maintain their traversal of this rejection for reasons of record as supplemented below.

The Examiner asserts that "[t]he amount of experimentation to make the claimed composition is enormous and undue and entails determining whether a particular disease is a lysosomal storage disorder disease, determining the etiology of the disease, and formulating a composition to treat or cure the disease." Office Action at page 3, par. 2. This assertion certainly cannot apply to claims to claims 9 and 10, which were previously amended to apply to one particular lysosomal storage disorder and one particular protein, respectively. The scope of the remaining claims has been limited to proteins listed in Table 1 of the specification by virtue of

the present amendment to claim 8. These proteins are clearly associated with the lysosomal storage disorder they can be used to treat in Table 1. Therefore practice of the claims, as amended, does not entail determining whether a particular disease is a lysosomal storage disorder and determining the etiology of the disease. This information is known and is provided in Table 1. As for formulating a composition to treat or cure the known protein deficiency for each lysosomal storage disorder, the specification clearly teaches the production of proteins in insect cells and formulation of compositions comprising such proteins using conventional techniques.

The Examiner further asserts that "[t]he specification does not teach any one particular protein/enzyme can be used to treat every lysosomal storage disorder as encompassed by the claims." Office Action at page 3, par. 2. Applicants agree that the specification does not provide such a teaching. Instead the specification teaches the specific protein deficiencies associated with each particular lysosomal storage disorder, thus revealing the protein(s) which can be made into a pharmaceutical composition to remedy the deficiency characteristic of that particular lysosomal storage disorder. Applicants do not agree that the claims encompass a single protein/enzyme for treating every lysosomal disorder and do not understand how the claims have been interpreted in this manner, particularly in light of the teachings in the specification. Rather the claims, read in light of the specification clearly cover, for example, the use of a composition comprising acid α-1,4 glucosidase and acid α-1,6 glucosidase to treat Pompe Disease, the use of β-galactosidase to treat GM1 Gangliodsidosis, etc. (see Table 1).

Reconsideration and withdrawal of this rejection is respectfully requested in view of the amendment to the claims and remarks above, as well as Applicants prior amendment and response submitted April 4, 2003.

V. Composition Limitations Inherent in the Process Used Cannot Be Ignored

On page 4 of the Office Action the Examiner has maintained his rejection of claims 8-13 under 35 U.S.C. §102(a) asserting that the claimed subject matter is anticipated by Sharp, J.D.,

international application no. PCT/US99/31158, published as WO 00/31950 ("Sharp"). Applicants respectfully maintain their traversal of this rejection for reasons of record as supplemented below.

In this rejection the Examiner appears to argue that the claims must recite the properties of the claimed composition which distinguish it from the compositions disclosed in Sharp. Such an argument reveals a failure to appreciate an essential purpose of the product-by-process claim format. This claim format allows a product with distinguishing properties that are difficult or impossible to articulate with specificity to be claimed according to the method of production which generates such distinguishing properties. Thus this claim format is specifically designed to avoid the need to recite specific distinguishing properties of a claimed composition in appropriate circumstances.

To the extent possible, Applicants have described in the specification the properties of the claimed compositions arising from production in insect cell culture which distinguish them from proteins produced by other means, including those disclosed in Sharp. Moreover, the fact that proteins produced in insect cell culture have unique attributes relative to proteins produced by other means is not a new concept and it is difficult for Applicant's to understand why the Examiner chooses to ignore this fact when making this rejection.

Applicants further note that the Examiner has used an incorrect standard to consider whether this anticipation rejection has been sufficiently rebutted. At page 4, paragraph 3 of the Office Action, the Examiner asserts that "Applicant must show an unobvious difference between the claimed invention and the composition taught by Sharp." To the contrary, any difference between a claimed invention and the cited prior art, whether obvious or not, is sufficient to overcome anticipation since a reference must disclose every element of a claim in order to be anticipatory. *In re Spada,* 15 USPQ2d 1655, 1657 (Fed. Cir. 1990); *Richardson v. Suzuki Motor Co.,* 9 USPQ2d 1913, 1920 (Fed. Cir. 1989), *cert. denied,* 110 S. Ct. 154 (1989). To the extent that the Examiner acknowledges differences between the claimed composition and the prior art,

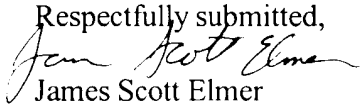
but intends to assert that such differences are obvious, then a new obviousness rejection should be made.

For the reasons set forth above and in the prior amendment and response submitted April 4, 2003, Applicants maintain that Sharp fails to teach a pharmaceutical composition comprising a protein that has the unique post-translational modifications associated with insect cell production and thus fails to anticipate the present product claims as properly construed to include limitations inherent in the insect cell production process used to make them. Reconsideration and withdrawal of this rejection on this basis is therefore respectfully requested.

VI. Conclusion

In view of the amendment to the claims and the remarks above, as well as the prior amendment and response submitted April 4, 2003, it is believed that the Examiner may properly withdraw all rejection of the claims under 35 U.S.C. §102 and §112, first paragraph. Having now fully responded to the Examiner's rejection of the claims, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit early notice of such favorable action. No fee is believed to be required for consideration of this submission. If applicants are incorrect and a fee is required the Commissioner is hereby authorized to charge such fee to Deposit Account No. 501968.

Respectfully submitted,



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